DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 11 2009

. I-011740-X-0006-CE

U.S. Fish & Wildlife Service
Aquatic Animal Drug Approval Partnership Program
Attention: David Erdahl, Ph.D.
Branch Chief
4050 Bridger Canyon Road
Bozeman, MT 59715

Re: Claim for a categorical exclusion for investigational use of benzocaine

Dear Dr. Erdahl:

Your claim for a categorical exclusion dated May 28, 2009, meets the criteria for categorical exclusion (CE) from the requirement to prepare an environmental assessment. The CE claim is for the investigational use of Benzoak (benzocaine) as an immersion (bath) treatment. The drug is proposed for investigational use in freshwater and marine finfish as an anesthetic. Please note that this letter only acknowledges your claim for a categorical exclusion. Your other request for an amended authorization will be addressed in a separate letter (O-0005). In the future, please submit only one request per letter.

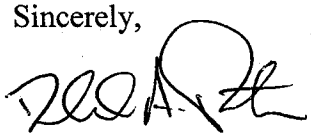
Your claim of categorical exclusion for the investigational use of benzocaine falls within the CE in 21 CFR 25.33(e). Your submission stated that to your knowledge no extraordinary circumstances exist that may significantly affect the human environment. Therefore, neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required. You are responsible for complying with the Federal Clean Water Act as implemented under the National Pollutant Discharge Elimination System (NPDES), as well as any applicable ground-water pollution requirements, for all investigational sites covered under this INAD. Prior to first use of benzocaine, you or your site investigator(s) must contact the authority responsible for issuing NPDES permits, or other similar state permits, to make them aware of the potential use and release of the investigational drug. In addition, this CE from the preparation of an EA and an EIS does not relieve you of the responsibility for determining and meeting all other Federal, State, and local environmental and occupational laws and regulations that apply to the manufacturing, use, and disposal of investigational drugs.

In the future, additional facilities may be added to the list in your study protocol without the need for a new CE request; however, all new facilities should be reported in your Quarterly and/or Annual reports. Please provide an assurance in these reports that you continue to meet the conditions of the CE (e.g., no extraordinary circumstances exist) for all investigational uses of benzocaine. You must request a new CE in the event there are changes to your study

protocol affecting the drug dosage or concentration, treatment duration, frequency of use, or indications of use such that environmental exposure at individual use sites will increase. In addition, if new information becomes available to you which indicates that extraordinary circumstances may exist as described in 21 CFR 25.21, you should inform CVM immediately so that we may determine if the CE continues to apply.

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact me at (240) 276-8177. You may also contact Charles Eirkson, at (240) 276-8173.

Sincerely,



Donald A. Prater, D.V.M.
Director, Division of Scientific Support
Office of New Animal Drug Evaluation
Center for Veterinary Medicine